

K101184

**510(k) Summary**

**ArthroCare Corporation  
Titan™ Ti Suture Anchor System**

**MAY 18 2010**

**General Information**

**Submitter Name/Address:** ArthroCare Corporation  
680 Vaqueros Avenue  
Sunnyvale, CA 94085-2936

**Establishment Registration Number:** 2951580

**Contact Person:** Valerie Defiesta-Ng  
Director, Regulatory Affairs

**Date Prepared:** April 27, 2010

**Device Description**

**Trade Name:** 5.5/6.5mm Titan Ti Suture Anchor  
Titan Bone Punch  
Titan Removal Tool Driver  
Titan Removal Tool Capture Sleeve

**Generic/Common Name:** Smooth or Threaded Metallic Bone  
Fixation Fastener (21 CFR 888.3040)

**Classification Name:** Class II, 21 CFR 888.3040  
Product Code MBI and HWC

**Predicate Devices**

Arthrocare Titan Ti Suture Anchor K092133 (November 5, 2009)

**Product Description**

The ArthroCare Titan Ti Suture Anchor is a fully-threaded, self-tapping, titanium corkscrew shape anchor available in 5.5mm and 6.5mm diameter sizes. The suture anchor comes preconfigured with MagnumWire® sutures and is mounted on a disposable delivery driver. The device is supplied sterile and is available with or without needles. The optional Titan instruments are used to facilitate implantation and removal of the Titan Ti Suture Anchor.

**Intended Uses/Indications for Use**

The Titan Ti Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist and elbow in the following procedures:

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- Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tendodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament/Tendon Repair, Bunionectomy;
- Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Iliotibial Band Tenodesis;
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction;
- Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair;
- Hip: Capsular Repair, Acetabular Labral Repair

#### **Substantial Equivalence**

The Titan Ti Suture Anchor design and technology is identical to the existing Titan Ti Suture Anchor devices cleared in K092133. The addition of ancillary instruments does not raise new questions regarding the safety and effectiveness of the Titan Ti Suture Anchor system. Efficacy of the device was shown in cadaver shoulder bone. The proposed system is safe and effective as the predicate device.

#### **Summary of Safety and Effectiveness**

The proposed modifications to the Titan Ti Suture Anchor System are not substantial changes, and do not significantly affect the safety or efficacy of the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center – WO66-0609  
Silver Spring, MD 20993-0002

ArthroCare Corporation  
% Ms. Valerie Defiesta-Ng  
Regulatory Affairs Director  
680 Vaqueros Avenue  
Sunnyvale, California 94085-3523

MAY 18 2010

Re: K101184

Trade/Device Name: ArthroCare® Titan™ Ti Suture Anchor System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: MBI  
Dated: April 27, 2010  
Received: April 28, 2010

Dear Ms. Defiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 - Ms. Valerie Defiesta - *Ny*

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson

Director

Division of Surgical, Orthopedic  
and Restorative Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number: K 101184

Device Name: ArthroCare® Titan™ Ti Suture Anchor System

### Indications for Use:

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Prescription Use  
(Part 21 CFR 801  
Subpart D)

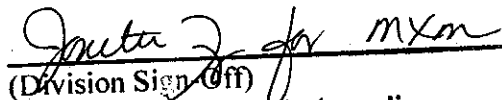
X

AND/OR

Over-the-Counter Use  
(21 CFR 807 Subpart  
C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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